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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,313	06/25/2003	Jin Lu	CEN0301	4892

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,313	LU ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 21 in part, 23-27, 28-31 in part, 36-38 in part, 39, and 40 in part, drawn to nucleic acids, vectors, host cells, and methods of making protein, classified in at least, for example, class 536, subclass 23.5.

II. Claims 13-20, 21 in part, 28-31 in part, 36-38 in part, and 40 in part, drawn to polypeptides, classified in at least, for example, class 530, subclass 350.

III. Claims 22, 28-31 in part, 36-38 in part, and 40 in part, drawn to antibodies, classified in at least, for example, class 530, subclass 387.1.

IV. Claims 32-35 in part, drawn to diagnostic methods employing nucleic acids, classified in class 435, subclass 6.

V. Claims 32-35 in part, drawn to methods of treatment employing nucleic acids, classified in class 514, subclass 44.

VI. Claims 32-35 in part, drawn to diagnostic methods employing proteins, classified in class 435, subclass 7.8.

VII. Claims 32-35 in part, drawn to methods of treatment employing proteins, classified in class 514, subclass 2.

VIII. Claims 32-35 in part, drawn to diagnostic methods employing antibodies, classified in class 435, subclass 7.1.

IX. Claims 32-35 in part, drawn to methods of treatment employing antibodies, classified in class 424, subclass 130.1.

2. It is noted that claims 21, 28-38 and 40 each recite nucleic acids, polypeptides, and antibodies in the alternative only. As nucleic acids, polypeptides and antibodies, as well as the various claimed methods employing them, constitute distinct inventions (for the reasons described below), each of claims 21, 28-38, and 40 have been included in multiple groups, and will be examined only to the extent they read upon the elected invention.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are drawn to patentably distinct products having different structures and functions. The polynucleotides of Group I are composed of nucleotides linked by phosphodiester bonds and function in, e.g., methods of hybridization. The proteins and antibodies of Inventions II and III, are each composed of amino acids linked by peptide bonds. However, these molecules have different functional properties and structural requirements. The antibodies of Invention III are glycosylated, have a particular tertiary structure, and have particular binding properties that render them distinct from other proteins. Further, while polypeptides are employed in, e.g., ligand binding assays or in the synthesis of antibodies, antibodies are employed, e.g., in cell labeling or in passive immunization. It is also noted that the nucleic acids of Invention I are not required to produce the proteins of Invention II, which proteins may be chemically synthesized or isolated from nature. Finally, searching more than one of Inventions I, II, and III would impose a serious search burden. Each invention requires

a different text and sequence search, and the consideration of different types of references. Accordingly, it would be burdensome to search more than one of these inventions.

Inventions I and IV, and I and V, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process, such as in methods of making proteins. Further, searching Inventions I and IV and/or I and V together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. Further, art relevant to the products of Invention I might or might not be relevant to the methods of Inventions IV and V, while Inventions IV and V require text searches unrelated to the products of Invention I.

Inventions I and VI, I and VII, I and VIII, and I and IX are unrelated because the product of Invention I is not used or otherwise involved in the process of Group VI, VII, VIII or IX.

Inventions II and IV, II and V, and II and IX are unrelated because the product of Invention II is not used or otherwise involved in the process of Group IV, V, or IX.

Inventions II and VI, II and VII, and II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process, such as methods of making antibodies. Further, searching Inventions II and VI and/or II and VII and/or II and VIII together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. Further, art relevant to the products of Invention II might or might not be relevant to the methods of Inventions VI, VII and VIII, while Inventions VI, VII, and VIII require text searches unrelated to the products of Invention II.

Inventions III and IV, III and V, and III and VII are unrelated because the product of Invention III is not used or otherwise involved in the process of Group IV, V, or VII.

Inventions III and VI, III and VIII, and II and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process, such as methods of protein isolation or cell labeling. Further, searching Inventions III and VI and/or III and VIII and/or II and IX together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. Further, art relevant to the products of Invention III might or might not be relevant to the

methods of Inventions VI, VIII and IX, while Inventions VI, VIII, and IX require text searches unrelated to the products of Invention III.

Inventions IV-IX are patentably distinct methods requiring different reagents and/or method steps to achieve different objectives. Invention IV requires the use of nucleic acids in "contacting" steps to achieve the objective of diagnosis. Invention V requires the administration of nucleic acids to achieve the objective of treatment. Invention VI requires the use of polypeptides in contacting steps to achieve the objective of diagnosis. Invention VII requires administration of polypeptides to achieve the objective of treatment. Invention VIII requires the use of antibodies in contacting steps to achieve the objective of diagnosis. Invention IX requires administration of antibodies to achieve the objective of treatment. A search of more than one of Inventions IV-IX would impose a serious burden. First, each method has a different status in the art as shown by the different classifications of Invention IV-IX. Further, searching more than one of the distinct inventions would be burdensome. It is noted that each of Inventions IV-V employs nucleic acids, that each of Inventions VI-VII employs polypeptides, and that each of Inventions VIII-IX employs antibodies; however, as the reagents of the claims are used in materially different steps to achieve differing objectives, each invention would require a separate search aimed at identifying different types of references. Further, while Inventions IV, VI, and VIII, and V, VII and IX share objectives of diagnosing and treating, respectively, the use in the Inventions of the distinct reagents of nucleic acids, polypeptides, and antibodies requires a different type

of text and sequence search for each invention, so as to identify references relevant to materially different types of methods of diagnosis/treatment.

Further restriction applicable to each of Groups I-IX

4. It is noted that each Group detailed above reads on numerous patentably distinct molecules. The numerous different nucleic acids, polypeptides, and antibodies encompassed by the instant claims are patentably distinct by virtue of having different sequences/structures, as well as different functional properties (for example, by virtue of hybridizing or binding to different target molecules or regions). As discussed in MPEP 803.04, absent evidence to the contrary, such molecules are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. A reference against one molecule would not be a reference against another, and, in view of this and the multitude of sequences submitted for examination by the USPTO, a search of SEQ ID NOS corresponding to more than one nucleic acid, encoding or depicting more than one polypeptide, or corresponding to more than one antibody would pose a serious burden. Accordingly, a further restriction is applied to each Group. Applicant must further elect a single nucleic acid, polypeptide, or antibody. More particularly, if electing a nucleic acid, Applicant should elect one of the SEQ ID Nos or subsequences of a SEQ ID NO (or combinations of subsequences) specified in the claims (see, e.g., claims 1-6 and 10-11), or, if electing a polypeptide, should elect one of the SEQ ID Nos or domains/domain combinations specified in the claims (see claims 12-13, 17-20). If electing an antibody, applicant should specify the SEQ ID NO/subsequence/domain combination to which the antibody specifically binds.

This is not an election of species. Applicant is advised that examination will be restricted to only the elected molecule.

5. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification and recognized divergent subject matter, and because Inventions I-IX require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

Species election

6. This application contains claims directed to the following patentably distinct species:

The 22 different compositions recited in claims 30 and 35.

The species are independent or distinct because each such composition (intended for co-administration as part of a therapeutic treatment) has a different structure and different functional characteristics. Thus, the different compositions are not, e.g., obvious variants that may be substituted one for the other, and art related to one such composition would not necessarily be pertinent to any other such composition. Each such species would require a different text search and the consideration of different types of prior art references, and thus a search of more than one such species would impose a serious search burden. Applicant is therefore required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. **Specifically,**

Applicant should elect a single composition from among those set forth in claims 30 and 35.

Currently, claims 28 and 32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Diana B. Johannsen
Primary Examiner
Art Unit 1634

3/20/06